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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,121	12/02/2003	Gregory Plowman	034536-0689	3038

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,121	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-12* is/are rejected.

7)☐ Claim(s) __ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/13/04, 10/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendment received September 30, 2005 is acknowledged.

Claims 1-12 are pending in the instant application.

Applicant's election with traverse of Group I, claims 1-6 and 9-12, as they read on antibodies that bind PAK5 and kits comprising said antibodies in the reply filed on September 30, 2005 is acknowledged. The traversal is on the ground that there is no burden to search the groups together. This is not found persuasive because of the reasons of record set forth in the restriction requirement mailed August 31, 2005. Applicant is reminded of the possibility of rejoinder as set forth in paragraph 6 of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction requirement in the reply filed on September 30, 2005.

Information Disclosure Statement

2. Applicant's IDS forms received February 13, 2004 and October 11, 2005 are acknowledged and have been considered.

Specification

3. Applicant is reminded to update the first line of the specification to indicate that USSN 09/688,188 has issued as US Patent No. 6,656,716 and that USSN 09/291,417 has issued as US Patent No. 6,680,170.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims are drawn to antibodies that bind a naturally occurring polypeptide sequence. As such, antibodies that recognize this polypeptide could also be found in nature as naturally occurring products. Amending the claims to show the involvement of the hand of man, such as that the antibodies have been purified or isolated, if support for such a limitation can be found in the specification, would overcome this rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, 5, and 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies that bind to a polypeptide comprising SEQ ID NO:30 or SEQ ID NO:103, and for kits comprising said antibodies wherein the labeled binding partner is a labeled secondary antibody or is a labeled polypeptide having the sequence of either SEQ ID NO:30 or 103, does not reasonably provide enablement for an antibody that binds any PAK5 polypeptide or kits comprising any labeled binding partner. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has claimed antibodies that bind to epitopes of a PAK5 kinase polypeptide and has disclosed the amino acid sequences of SEQ ID NO:30 and 103 as PAK5 sequences (see entire document particularly paragraph 324 on page 77, paragraph 115 on page 34 and Figure 8G). The specification teaches that the polypeptides bound by antibodies may consist of the aforesaid full length sequences, functional derivatives thereof, or at least 9 contiguous amino acids thereof (see particularly paragraph 333 that begins on page 78). The term "functional derivative" does not appear to be defined in the specification, but reasonably such a term could include peptides of modified sequence, peptides containing non-naturally occurring

amino acids, and non-peptide molecules such as small organic compounds that retain the function of the original peptide sequence. The specification does not indicate that the polypeptides bound by the claimed antibodies retain any kinase activity, and as such the only functional property of the peptides is that they can be detected by antibody binding. However, the specification indicates that antibodies that bind PAK5 are to be used in diagnostic methods to detect the presence of PAK5 in patient samples (see particularly paragraphs 68, 345-349). As such, the claimed antibodies must be capable of binding to the native, wild type sequence of PAK5 that is found in patients. Colman et al. teaches that even single amino acid changes in an antigen can abolish the binding of an antibody to the antigen (Research in Immunology, (1994) 145:33-36, see entire document, particularly the right column of page 33), and the specification does not appear to define a core structure that must be maintained by PAK5 kinase polypeptides to ensure that antibodies recognizing these kinase peptides also bind to the native sequence of the PAK5 polypeptide. Therefore, it appears that while applicant is in possession of antibodies that bind to epitopes found completely within SEQ ID NO:30 and SEQ ID NO:103, applicant was not in possession of the entire genus of antibodies that bind PAK5 kinase polypeptides as defined by the specification.

Applicant has also claimed kits that comprise "labeled binding partners" of antibodies that bind a PAK5 kinase polypeptide. The term "labeled binding partners" does not appear to be defined by the specification, and this term appears to differ in scope from the term "detection reagents". The specification in paragraphs 348-349 of page 82 and dependent claims 10 and 12 both indicate that the kit contains the "labeled

binding partner" and additionally comprises detecting reagents such as labeled secondary antibodies (see particularly paragraph 349). However, it is not clear if reagents such as secondary antibodies are meant to be encompassed by the term "binding partner" since secondary antibodies specifically bind the claimed antibodies and it does not appear to be taught that the "binding partner" must interact with the claimed antibody via the variable domains (i.e. antigen binding domain) of the claimed antibodies. The breadth of molecules that reasonably can interact with the claimed antibodies through binding via the antibody variable domains includes PAK5 kinase polypeptides. The amount to which such molecules as defined by the specification have been described by the instant specification has been addressed above in the discussion concerning PAK5 kinase polypeptides and their "functional derivatives".

Therefore, given that the specification does not appear to describe a core structure that must be recognized by the claimed antibodies such that they bind to both native wild type PAK5 as well as the genus of PAK5 kinase polypeptides as disclosed in the specification, and the apparent lack of a definition of what constitutes a "binding partner" of the claimed antibodies, it appears that applicant has failed to adequately disclose what would be required for a skilled artisan to recognize an antibody that binds the genus of PAK5 kinase antibodies and to recognize all "labeled binding partners" of said antibody. Thus, Applicant was not in possession of the claimed genus of antibodies and binding partners. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description"

Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hybridoma that produces an antibody, does not reasonably provide enablement for a hybridoma that produces an antibody fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has claimed hybridomas that secrete whole antibody as well as antibody fragments. Janeway et al. teach that hybridomas secrete whole antibody molecules, and that fragments of antibodies can be produced through phage display technology of by fragmentation of whole antibody with enzymes such as papain (Immunobiology, third edition, see entire selection particularly Figures 2.16, 2.17, and Figure 3.4). As such, a skilled artisan would be unable to obtain antibody fragments directly from hybridomas without conducting additional research.

8. Before setting forth any rejections based upon the prior art, the question of benefit of the instant claims to earlier filed applications must be addressed.

The instant specification appears to define PAK5 as the full length polypeptide sequence of SEQ ID NO:103 (see particularly paragraph 324 on page 77) and as the

partial sequence of SEQ ID NO:30 (see particularly Figure 8G and paragraph 115 on page 34). SEQ ID NO:30, and antibodies that bind this sequence, are supported by the disclosure of US provisional application 60/081,784 filed April 14, 1998. The full length sequence of SEQ ID NO:103 is not supported until the filing of nonprovisional application 09/291,417 on April 13, 1999. A claim can only have one date in its relation to prior art, and given that the full scope of the term PAK5 polypeptide as used in the instant specification is not supported until the disclosure of SEQ ID NO:103 in application 09/291,417, the date given to claims 1, 2, 5, 9, and 10 in relation to the prior art is April 13, 1999, the date on which application 09/291,417 was filed. Claims 3, 4, 6, 11, and 12 recite that the polypeptide comprises SEQ ID NO:30, and given that SEQ ID NO:30 and antibodies that bind SEQ ID NO:30 were disclosed in provisional application 60/081,784, the date given to these claims in relationship to the prior art is April 14, 1998.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Minden (US Patent 6,013,500, of record as reference A10 on the IDS received 2/13/04, see entire document).

Minden discloses a kinase named PAK4 that is 100% identical to the full length polypeptide of PAK5 disclosed in the instant application as SEQ ID NO:103 (see enclosed copy of the sequence search notes). Minden also discloses monoclonal antibodies specific for epitopes of this kinase, as well as hybridomas that produce said monoclonal antibodies (see particularly lines 31-32 of column 3 and from line 20 of column 9 to line 4 of column 10). The antibodies of Minden are disclosed as being detectable using labeled binding partners (see particularly lines 5-23 of column 10) and being present in pharmaceutical compositions (see particularly lines 34-44 of column 11 and lines 8-67 of column 12 and lines 1-45 of column 13).

Therefore, the prior art anticipates the claimed invention.

It should be noted that Minden filed her application on May 21, 1998 disclosing the full length sequence prior to the disclosure by applicant of SEQ ID NO:103 on April 13, 1999. Amending the claims so that the scope of the claims are full supported by applicant's provisional application disclosing the partial sequence identified as SEQ ID NO:30 would remove this rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minden (US Patent 6,013,500, of record as reference A10 on the IDS received 2/13/04, see entire document) in view of MacDonald et al. (US patent 5,366,889, see entire document).

The teachings of Minden have been discussed above. These teachings differ from the claimed invention in that Minden does not explicitly indicate a kit comprising an anti-PAK antibody in one container and a second container comprising a labeled binding partner.

MacDonald et al. teach kits comprising a) a first container comprising an antibody and b) one or more additional containers comprising wash reagents or agents capable of detecting the presence of bound antibodies from the first container (see entire document, particularly lines 36-45 of column 21). Reagents capable of detecting antibodies are disclosed by MacDonald et al. and can be reasonably considered "labeled binding partners" since labeled secondary antibodies are disclosed (see particularly lines 16-29 of column 22). The kits of MacDonald et al. offer the advantage of allowing efficient transfer of reagents from one compartment to another compartment to avoid cross-contamination and to allow for the addition of reagents in a quantitative fashion (see particularly lines 62-67 of column 21).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to place the antibodies and detection reagents taught by

Minden into a kit form to gain the advantage of allowing for the efficient transfer of reagents in a quantitative fashion that avoids cross-contamination of the reagents.

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
November 28, 2005

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600